

*SAC*  
*BT*

2) where the long lag pellet substantially exhibits the following dissolution profile when measured according to U.S. Pharmacopeia XXII in a type 2 dissolution apparatus at 37° C in 0.1N HCl at 100 rpm:

- a) 0 to 10% of the diltiazem is released after 2 hours;
- b) 0 to 10% of the diltiazem is released after 4 hours;
- c) 0 to 15% of the diltiazem is released after 6 hours;
- d) 0 to 15% of the diltiazem is released after 8 hours;
- e) 4.5% to 24.5% of the diltiazem is released after 14 hours;
- f) 41% to 61% of the diltiazem is released after 16 hours; and
- g) more than 60% of the diltiazem is released after 18 hours.

61/92. A long lag pellet suitable for use in a once-a-day diltiazem formulation comprising:

1) a core comprising an effective amount of diltiazem or a pharmaceutically acceptable salt, the core being substantially free of organic acid;

2) where the long lag pellet substantially exhibits the following dissolution profile when measured according to U.S. Pharmacopeia XXII in a type 2 dissolution apparatus at 37° C in 0.1N HCl at 100 rpm:

- a) 0 to 10.3% of the diltiazem is released after 2 hours;
- b) 0 to 10.5% of the diltiazem is released after 4 hours;
- c) 0 to 10.7% of the diltiazem is released after 6 hours;
- d) 0 to 10.9% of the diltiazem is released after 8 hours;
- e) 4.5% to 24.5% of the diltiazem is released after 14 hours;
- f) 41% to 61% of the diltiazem is released after 16 hours; and

g) more than 60% of the diltiazem is released after 18 hours.

62 93. A once-a-day diltiazem formulation for oral administration comprising a mixture of two types of pellets, one of which is a long lag pellet that comprises:

- 1) a core comprising an effective amount of diltiazem or a pharmaceutically acceptable salt, the core being substantially free of organic acid;
- 2) and substantially exhibits the following dissolution profile when measured according to U.S. Pharmacopeia XXII in a type 2 dissolution apparatus at 37° C in 0.1N HCl at 100 rpm:

- a) 0 to 10% of the diltiazem is released after 2 hours;
- b) 0 to 10% of the diltiazem is released after 4 hours;
- c) 0 to 15% of the diltiazem is released after 6 hours;
- d) 0 to 15% of the diltiazem is released after 8 hours;
- e) 4.5% to 24.5% of the diltiazem is released after 14 hours;
- f) 41% to 61% of the diltiazem is released after 16 hours; and
- g) more than 60% of the diltiazem is released after 18 hours.

63 94. A once-a-day diltiazem formulation for oral administration comprising a mixture of two types of pellets, one of which is a long lag pellet that comprises:

- 1) a core comprising an effective amount of diltiazem or a pharmaceutically acceptable salt, the core being substantially free of organic acid;
- 2) and substantially exhibits the following dissolution profile when measured according to U.S. Pharmacopeia XXII in a type 2 dissolution apparatus at 37° C in 0.1N HCl at 100 rpm:
  - a) 0 to 10.3% of the diltiazem is released after 2 hours;

*Sud  
Cz  
Cmt*

- b) 0 to 10.5% of the diltiazem is released after 4 hours;
- c) 0 to 10.7% of the diltiazem is released after 6 hours;
- d) 0 to 10.9% of the diltiazem is released after 8 hours;
- e) 4.5% to 24.5% of the diltiazem is released after 14 hours;
- f) 41% to 61% of the diltiazem is released after 16 hours; and
- g) more than 60% of the diltiazem is released after 18 hours.

*64 95.* A long lag pellet according to claims 91 through 94 where 14.5% to 24.5% of the diltiazem is released after 14 hours.

*65 96.* A long lag pellet according to claims 91 through 94 where 51% to 61% of the diltiazem is released after 14 hours.

*B+* *66 97.* A long lag pellet according to claims 91 through 94 where 41% to 51% of the diltiazem is released after 14 hours.

*67 98.* A long lag pellet according to claims 91 through 94 where 14.5% to 24.5% of the diltiazem is released after 14 hours and 51% to 61% of the diltiazem is released after 14 hours.

*68 99.* A long lag pellet according to claims 91 through 94 where 14.5% to 24.5% of the diltiazem is released after 14 hours and 41% to 51% of the diltiazem is released after 14 hours.

*69 100.* A long lag pellet according to claims 91 through 94 where

- a) 0-10.3% of the diltiazem is released after 1 hour;
- b) 0-11.3% of the diltiazem is released after 10 hours; and
- c) 0-13.1% of the diltiazem is released after 12 hours

*70 101.* A long lag pellet according to claims 91 through 94 where